

Application No.: 10/808,113

Reply to Office Action of: November 16, 2005

CLAIMS

The current claim set of the application is presented below. Indications as to the status of the claims ("original", "currently amended", "cancelled", "new", etc.) appear in parentheses after the claim number. Deletions are identified in bold with double brackets and strikethrough (e.g. ~~[[deletion]]~~) and new text is identified in bold with underlining (e.g. **new language**).

1. (original) A process for preparing an injectable pharmaceutical composition comprising gabapentin, the process comprising:
preparing an injectable composition comprising gabapentin and a pharmaceutically acceptable vehicle; and
heating the injectable composition to produce the injectable pharmaceutical composition.
2. (original) The process of claim 1, wherein the heating sterilizes the composition.
3. (original) The process of claim 1, further comprising filtering the injectable composition.
4. (original) The process of claim 3, further comprising aseptically placing the filtered composition in a container to produce a container housing the filtered composition.
5. (original) The process of claim 4, wherein the heating comprises heating the container housing the composition.
6. (original) The process of claim 1, further comprising adjusting the pH of the injectable composition.
7. (original) The process of claim 1, wherein the heating comprises autoclaving.
8. (original) The process of claim 1, wherein the heating comprises heating the injectable composition at greater than or equal to about 105°C for greater than or equal to about 2 minutes.

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9. (original) The process of claim 8, wherein the heating comprises heating the injectable composition at between about 105°C and about 140°C for between about 2 minutes and about 60 minutes.
10. (original) The process of claim 9, wherein the heating comprises heating the injectable composition at greater than or equal to about 121°C for about 24 minutes.
11. (original) The process of claim 9, wherein the heating comprises heating the injectable composition at greater than or equal to about 130°C for about 4 minutes.
12. (original) The process of claim 9, wherein the heating comprises heating the injectable composition at greater than or equal to about 118°C for between about 6 minutes to about 8 minutes.
13. (original) The process of claim 1, wherein the injectable composition is heated to an F_0 of about 1 or greater.
14. (original) The process of claim 13, wherein the injectable composition is heated to an F_0 of about 2 or greater.
15. (original) The process of claim 14, wherein the injectable composition is heated to an F_0 of about 3 or greater.
16. (original) The process of claim 15, wherein the injectable composition is heated to an F_0 of about 4 or greater.
17. (original) The process of claim 16, wherein the injectable composition is heated to an F_0 of about 8 or greater.
18. (original) The process of claim 17, wherein the injectable composition is heated to an F_0 of about 12 or greater.

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19. (original) The process of claim 18, wherein the injectable composition is heated to an F_0 of about 18 or greater.
20. (original) The process of claim 19, wherein the injectable composition is heated to an F_0 of about 24 or greater.
21. (original) The process of claim 1, wherein the injectable pharmaceutical composition comprises less than or equal to about 10% (w/v) gabapentin lactam.
22. (original) The process of claim 21, wherein the injectable pharmaceutical composition comprises less than or equal to about 5% (w/v) gabapentin lactam.
23. (original) The process of claim 22, wherein the injectable pharmaceutical composition comprises less than or equal to about 2% (w/v) gabapentin lactam.
24. (original) The process of claim 23, wherein the injectable pharmaceutical composition comprises less than or equal to about 1% (w/v) gabapentin lactam.
25. (original) The process of claim 1, wherein the injectable pharmaceutical composition comprises between about 0.5% (w/v) and about 10% (w/v) gabapentin lactam.
26. (original) The process of claim 1, wherein the injectable pharmaceutical composition comprises between about 0.1 mg/ml and about 100 mg/ml gabapentin.
27. (original) The process of claim 26, wherein the injectable pharmaceutical composition comprises between about 30 mg/ml to about 100 mg/ml gabapentin.
28. (original) The process of claim 27, wherein the injectable pharmaceutical composition comprises about 80 mg/ml gabapentin.

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29. (currently amended) The process of claim 1, wherein the injectable pharmaceutical composition comprises between about 10 mg/ml and about 50 mg/ml [~~gababentin~~]
gabapentin.
30. (currently amended) The process of claim 1, wherein the injectable pharmaceutical composition comprises between about 20 mg/ml and about 40 mg/ml [~~gababentin~~]
gabapentin.
31. (currently amended) The process of claim 1, wherein the injectable pharmaceutical composition comprises about 30 mg/ml [~~gababentin~~] gabapentin.
32. (original) The process according to claim 6, wherein the pH is adjusted by adding sodium hydroxide, hydrochloric acid, or both to the injectable composition.
33. (original) A process for preparing an injectable pharmaceutical composition comprising gabapentin, the process comprising:
preparing an injectable composition comprising gabapentin and a pharmaceutically acceptable vehicle;
adjusting the pH of the injectable composition;
filtering the pH-adjusted injectable composition;
aseptically placing the filter-sterilized composition into a container; and
heating the container housing the composition to produce the injectable pharmaceutical composition.
34. (original) The process according to claim 33, wherein the injectable pharmaceutical composition is substantially free of preservatives and substantially free of buffers.
35. (original) The process of claim 33, wherein the filtering comprises filtering the pH adjusted injectable composition through a filter having a pore size of about 0.22 μ m.

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36. (original) The process of claim 33, wherein the process produces a composition having a level of sterility equivalent to a composition heated to an F_0 of about 8 or greater.
37. (original) The process of claim 33, wherein the process produces a composition having a level of sterility equivalent to a composition heated to an F_0 of about 24 or greater.
38. (original) The process of claim 33 wherein the heating comprises heating to a temperature of greater than or equal to or about 105°C.